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Lab Groups Weigh in on Health Care Reform Proposals

Another legislative focus for the lab industry this year is to ensure that Medicare lab fees get their scheduled CPI update in 2010. With Congress expected to approve a Medicare physician fee increase, lab groups want to make sure that cuts are not made in Part B spending to help pay for it.

As Senate and House committees gear up to consider health care reform bills this month, the Clinical Laboratory Coalition (CLC) has been quick to pitch its priorities in the run-up to legislative action. CLC members include national lab associations, national lab companies, and device manufacturers.

In comments to Congress and the White House, the coalition urges that clinical lab testing be specifically included in any health benefits package, with no patient copay, and that incentives be provided to promote wellness and prevention programs and personalized medicine.

The health care reform debate is a rare opportunity to raise issues beyond reimbursement, says Vince Stine, Ph.D., director of government affairs for the American Association for Clinical Chemistry. "Typically we are on the chopping block. Now, we can paint a larger picture of our role and interests in improving health care," he told *NIR*.

Mark Birenbaum, administrator of the American Association of Bioanalysts, agrees that health care reform is a new and challenging legislative focus for the industry. "We will be watching to see how labs fit into the proposals being considered," he told *NIR*. For more on the major issues, see the *Focus*, pp. 4-6.

Health IT Bonus Alert for Pathologists

Under provisions of the American Recovery and Reinvestment Act of 2009 (ARRA), Medicare and Medicaid bonuses are payable to qualified pathologists and other eligible professionals and to hospitals if they adopt and make meaningful use of certified health information technology (HIT) systems, including electronic health records (EHRs), starting in 2011.

Medicare-participating independent pathologists are entitled to HIT incentive payments of up to $44,000 over five years. Hospital-based pathologists who participate in Medicare are barred from receiving direct payments. They are covered under the hospital's incentive payments. The determination of "hospital-based" depends on the site of service, whether inpatient or outpatient, and without regard to any employment or billing arrangements.

But in unveiling its plan to implement the HIT bonus program, the U.S. Department of Health and Human Services (HHS) cautioned that significant issues must be resolved if the statutory timetable is to be met.

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The HIT bonus program is limited by law to hospitals, physicians, and other eligible professionals. Clinical laboratories are not entitled to direct payments. Lawmakers instead called for a study, due by June 30, 2010, to determine whether they and other health care providers should get direct HIT bonuses.

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The bonuses to qualified pathologists and other eligible professionals who make meaningful use of certified EHR systems are payable during calendar years 2011 to 2014 and to hospitals during fiscal years 2011 to 2015. Providers must choose to be paid by either Medicare or Medicaid.

Issues in Implementation

If implementation is to run smoothly, HHS noted, decisions and follow-up action on a number of fronts must be accomplished quickly. These include defining criteria to meet the statutory requirements for certified EHR systems and meaningful use, along with establishing state systems to support the incentive programs, and ensuring accurate reporting by states and providers.

The most pressing front, said HHS, is defining the terms "certified EHR systems" and "meaningful" user. The secretary is required to do so by Dec. 31 of this year in an interim final rule setting forth the performance standards required to begin provider incentive payments in 2011.

The law sets forth broad criteria to determine meaningful use of HIT, including certified EHR systems. This can be done, according to ARRA, through a variety of means, such as the reporting of quality measures, use of e-prescribing systems, submission of claims with coding indicating that an HIT system was used as part of the service, and other alternatives deemed appropriate by the HHS secretary. The law leaves it up to the secretary to define meaningful use.

Calculating the Bonuses

Medicare bonuses to pathologists and other eligible professionals will be calculated on 75 percent of allowable charges for the services they furnished during the payment year, not to exceed the payment maximums set by law. Payments will be made from 2011 through 2016. Bonuses are increased by 10 percent for those providing services in a health professional shortage area.

The bonuses to pathologists and other eligible professionals are capped at a maximum of $44,000 over five years as follows:

- For the first payment year, $15,000. If this year for an eligible physician is 2011 or 2012, the payment is $18,000.
- For the second payment year, $12,000.
- For the third payment year, $8,000.
- For the fourth payment year, $4,000.
- For the fifth payment year, $2,000.
- For any succeeding payment year, $0.

The law penalizes those who are not a meaningful EHR user. They will see their Medicare payments reduced by 1 percent in 2015, 2 percent in 2016, and 3 percent in 2017 and thereafter. For 2018 and each subsequent year, the HHS secretary may make the cut deeper, but not below 95 percent.

An exemption is allowed, on a case-by-case basis, if the secretary determines that compliance with the requirement would result in significant hardship—such as in a rural area without sufficient Internet access. But in no case may an eligible professional be exempt for more than five years.

HHS Appoints Members to New Health IT Advisory Panels

The U.S. Department of Health and Human Services (HHS) has announced its appointments to two new committees established to advise the government on steps to promote nationwide adoption of health information technology (HIT), a health care reform priority of the Obama administration and Congress.

The department appointed three members to the HIT policy committee and 23 to the HIT standards committee. The committees were established by the American Recovery and Reinvestment Act of 2009 (ARRA) as part of the federal infrastructure to spur adoption of electronic health records to improve the quality of care, reduce medical errors, and lower health care costs.

Nominees by the American Clinical Laboratory Association did not make the final cut. ACLA nominated its president, Alan Mertz, for the policy panel and Ken McCaslin, senior health care standards architect at Quest Diagnostics, for the standards committee. ACLA pushed for lab industry representation on both committees, noting that lab test results account for 60 percent of the electronic medical record and that labs, in particular independent labs, have extensive experience in establishing e-links to thousands of physician offices (*NIR, 09, 7/Apr. 13, p. 3*).

HIT Policy and Standards Committees

The HHS appointees to the policy committee are:

- David Blumenthal, M.D., M.P.P., national coordinator for HIT at HHS
- Michael J. Klag, M.D., M.P.H., dean, Johns Hopkins Bloomberg School of Public Health
- Deven C. McGraw, J.D., M.P.H., director, Health Privacy Project, Center for Democracy and Technology

An additional 13 members were chosen by the acting comptroller general, with four others selected by the congressional Democratic and Republican leadership. The presidential appointments from relevant federal agencies had yet to be announced at press time.

The HIT policy committee is charged with making recommendations to the national HIT coordinator on implementation of a nationwide HIT infrastructure, including areas where standards, implementation specifications, and certification criteria are needed, including measures to assure the privacy and security of an individual's protected health information.

Appointments to the HIT standards committee reflect a cross-section of stakeholders, including hospital systems, medical clinics, medical schools, private payers, consumers, and research institutes. Representatives from relevant federal agencies have yet to be selected, HHS noted.

For information and updates on the HHS health IT initiative, go to http://healthit.hhs.gov.

The HIT standards committee is charged with advising the national HIT coordinator on standards, implementation specifications, and certification criteria. It shall, as appropriate, provide for the testing of standards and specifications by the National Institute for Standards and Technology. Within 90 days of receiving the committee's recommendations from the national coordinator, the HHS secretary is to consult with other relevant federal agencies on whether to propose their adoption. The secretary is required to adopt, through rulemaking, an initial set of standards by Dec. 31, 2009.

focus on: Health Care Reform

Obama: It's 'Make or Break' Time for Health System Overhaul

President Barack Obama is urging Congress to act on health care reform legislation by the August recess and get a final version to his desk for signing in October. Toward this end, Democratic leaders of House and Senate health committees are aiming to come up with their first draft by the end of this month.

"The next few months are a critical period," the president said June 2 after meeting with Democratic members of the Senate Finance and Health, Education, Labor, and Pensions (HELP) committees. "It will be a heavy lift. But I am confident that people want to get it done. Health care reform is not a luxury, it is a necessity," noting that rising costs in health care are "unsustainable for families, businesses, and government."

In a follow-up June 3 letter to the committee chairmen Max Baucus and Edward Kennedy, Obama stressed that "reform cannot mean focusing on expanded coverage alone. Without a serious, sustained effort to reduce the growth rate of health care costs, affordable health care coverage will remain out of reach. So we must attack the root causes of inflation in health care. That means promoting the best practices, not simply the most expensive."

Laboratory testing plays an essential role in supporting health care reform goals of improving quality while reducing unnecessary costs. Lab test results inform up to 70 percent of all medical decisionmaking. As the first point of intervention, lab tests serve as the foundation for the diagnosis and treatment of conditions such as cardiac disease, HIV, cancer, diabetes, kidney disease, and infectious diseases—Clinical Laboratory Coalition, 2009 health care reform principles.

Underscoring cost concerns, a private study released June 4 found medical bills to be a major contributor to the growing number of bankruptcies—62 percent in 2007, while the proportion of all bankruptcies linked to illness rose by nearly 50 percent since 2001. The vast majority of those affected were privately insured, but liable for thousands of dollars in out-of-pocket expenses.

Rising health care costs are a big factor bringing all the main players to the reform table, according to Vince Stine, government affairs director for the American Association for Clinical Chemistry (AACC). "Yet there is no foolproof way to finance it," he told *NIR*. "If you hold to the pay-as-you-go approach, we are talking trillions of dollars." Financing options floated to date have been highly controversial, including capping the tax exclusion of benefits, limiting itemized deductions for charitable contributions, and capturing savings by introducing competitive bidding into Medicare managed care, reducing hospital readmission rates, and bundling payments for hospital and post-acute care.

Lab Industry Jumps In

As the Senate health committees and their House counterparts sift through reform proposals, members of the Clinical Laboratory Coalition (CLC, see box, p. 6) have joined the debate, releasing a set of principles and specific proposals in areas where clinical lab testing needs to be addressed. Coalition members also have been meeting with committee staff to further discuss how their priorities contribute to the broad reform goals of improving quality and lowering costs.

In its statement of principles, CLC says any expansion of access to health care must include patients' access to lab services, including wellness and prevention services. Reform also should foster innovations in diagnostic technologies that enhance quality care and reimburse these innovations adequately. The coalition advocates broader availability of personalized medicine, which enables physicians to select the most appropriate test, detect disease earlier, and determine the optimal therapy. CLC backs incentives for co-development of drugs and lab tests and adoption of electronic health records, as well as reimbursement for genetic tests at a level that fully recognizes their value.

With expanded coverage, demand for lab testing will increase, and this means more data will be transmitted electronically between labs and providers, CLC notes. "It is essential that electronic health record systems be integrated and interoperable," and that labs qualify for current and future health information technology grants and other federal support. Expanded coverage will also require sufficient qualified health care personnel to serve patient needs, CLC points out. Given the growing shortage of lab professionals and the increasing age of the current workforce, the coalition calls for a federal initiative to expand the lab personnel pool by fully funding the Title VII health professions programs.

CLC Comments on Proposed Options

In response to option papers circulated by the Finance Committee during a series of roundtable discussions on health care coverage and financing, the lab coalition recommended revisions to specific proposals being considered, as follows:

Option: Expand coverage and make it affordable.

Add clinical laboratory diagnostic testing and screening to the basic medical benefit that all health insurance plans in the nongroup and small-group market would have to provide. In addition, plans should not be allowed to include lifetime limits on coverage or annual limits on benefits or require patient cost sharing, even in nominal amounts, for preventive care services.

Option: Promotion of prevention and wellness in Medicare

Add the conduct of appropriate clinical laboratory testing to the elements of a personalized prevention plan. This option would authorize Medicare payment for a visit to a qualified health professional to create such a plan. CLC says the benefit should include referrals for additional diagnostic tests as indicated by the plan.

Option: Incentives for preventive services

Rely on more than the U.S. Preventive Services Task Force in determining coverage of preventive services. The CLC says this option should be expanded to include "services recommended by the Advisory Committee on Immunization Practices, National Institutes of Health, Centers for Disease Control and Prevention, Institute of Medicine, specialty medical associations, patient groups, scientific societies, or the Clinical Laboratory Improvement Advisory Committee (CLIAC)."

Option: Expand beneficiary cost sharing.

One proposal in the options paper on financing called for "consistent cost sharing and a combined annual deductible covering all Part A and Part B services." The lab coalition says this leaves open the possibility of imposing a uniform 20 percent copay for preventive and diagnostic clinical lab services that are not currently subject to coinsurance. A lab copay is at odds, CLC said, with the Finance Committee's stated

goals to promote prevention and wellness and would add a new cost burden on beneficiaries as well as add to labs' billing costs.

Outlook for Action

"The chances for action on health care reform this year are better than in previous years," AACC's Stine told *NIR*, "though it is always possible it may not pan out," at least on as comprehensive a scale as some would hope. The political dynamics are vastly different, he said, from those in 1993, the last year in which comprehensive reform was attempted. Then, the White House led the effort, working behind closed doors to develop a plan. But even before the plan was out, it was fiercely attacked by businesses and insurers, and with scant support from Congress, the Clinton administration effort collapsed.

This time, Stine noted, Obama is letting Congress take the lead in thrashing out the details. "The key issue is how Congress can accommodate the stakeholders and get them to buy in early on." While he sees a "greater pragmatism" on the part of stakeholders, he said the real test comes when the details emerge and they are faced with making compromises where their interests conflict, especially on how to share the cost of financing reform. "We are still in the euphoric stage," he said, "and there is a lot of hard bargaining ahead."

Work by the Senate and House health committees has reflected broad agreement on the basic elements of reform: an individual mandate to purchase health care coverage as affordable options become available; a requirement that employers cover employees or pay a portion of payroll into a purchasing pool; guaranteed issuance and renewal of coverage by private insurers, with no restrictions based on pre-existing conditions; a new public plan that would compete with private insurers; a national health information exchange to help consumers shop for affordable coverage; and premium subsidies, based on a sliding scale, to help low-income individuals and families purchase coverage.

In the June 3 letter to Baucus and Kennedy, Obama said he is open to an individual mandate, which he opposed during his campaign, but said it should be waived for those who cannot afford it. While supporting an employer mandate, he said small businesses should be exempt. He gave strong support to the proposed new public plan, saying, "This will give Americans a better range of choices, make the market more competitive, and keep insurers honest."

Absent from the deliberations thus far is the single-payer option. Baucus has said this is not politically feasible and "off the table," but he has met with its backers to discuss the issue. One of the main backers, the California Nurses Association, says health care reform should not leave private insurers at the apex of power in the system. Sen. Bernie Sanders (I-Vt.), a single-payer supporter, said he hopes the Senate will at least hold a hearing on this approach. "I find it incomprehensible that if we are serious about tackling outrageously high costs, we are not engaging in serious discussion about a single-payer system."

Clinical Laboratory Coalition

- ❑ American Association of Bioanalysts
- ❑ American Association for Clinical Chemistry
- ❑ American Clinical Laboratory Association
- ❑ American Medical Technologists
- ❑ American Society for Clinical Laboratory Science
- ❑ American Society for Microbiology
- ❑ Becton, Dickenson and Co.
- ❑ Clinical Laboratory Management Association
- ❑ Laboratory Corp. of America Holdings
- ❑ National Independent Laboratory Association
- ❑ Quest Diagnostics Inc.
- ❑ Roche Diagnostics
- ❑ Sonic Healthcare USA

♦ Medicare Claims *Advisory*

'Date of Service' Clarified for Pathology Global Billing

The Centers for Medicare and Medicaid Services (CMS) has ruled that global billing is "not appropriate" for the professional component (PC) and the technical component (TC) of pathology services performed by the same independent laboratory, but on different dates of service. In this case, the TC and the PC are to be billed as separate line items.

CMS clarified the policy in response to a question from a commenter on the rule establishing a new date of service (DOS) for the pathology TC (Change Request 6018, May 21, 2008). The agency alerted Medicare contractors that it is adding the revised DOS policy on pathology billings to its manual instructions, effective Aug. 24, 2009 (Change Request 6457, Revision 1744).

As a general rule, the DOS for either the TC of pathology services or a clinical laboratory test is the date the specimen was collected. If a specimen is collected over a period that spans two calendar days, the DOS must be the date the collection ended.

There are two exceptions. If a specimen was stored for 30 calendar days from the date it was collected or less, the DOS must be the date the test was performed only if:

- ❑ The test is ordered by the patient's physician at least 14 days following the date of the patient's discharge from the hospital;
- ❑ The specimen was collected while the patient was undergoing a hospital surgical procedure;
- ❑ It would be medically inappropriate to have collected the sample other than during the hospital procedure for which the patient was admitted;
- ❑ The results of the test do not guide treatment provided during the hospital stay; and
- ❑ The test was reasonable and medically necessary to treat an illness.

If the specimen was stored for more than 30 calendar days before testing, the specimen is considered to have been archived, and the DOS of the test must be the date the specimen was obtained from storage.

The other exception applies to the DOS for chemotherapy sensitivity tests performed on live tissue. The DOS must be the date the test was performed under the conditions for stored specimens noted above. A "chemotherapy sensitivity test" is defined as one that requires a fresh tissue sample to test the sensitivity of tumor cells to various chemotherapeutic agents. CMS identifies these tests through program instructions to Medicare contractors.

Meantime, the American Clinical Laboratory Association is advocating another revision to Medicare DOS policy. It supports House legislation (H.R. 1699) that would allow an independent laboratory to be paid directly by the program for complex molecular and genetic tests performed after a hospital outpatient encounter or inpatient stay during which the specimen involved was collected. "Today, when a lab test is ordered within 14 days of discharge, the hospital, not the lab, must bill Medicare for the service," ACLA said, "creating access problems for this category of tests that are ordered after the patient's hospital stay" (*NIR, 09, 7/Apr. 13, p. 5*).

Should MedPAC Have More Say in Medicare Payment Policy?

MedPAC's recommendations already are influential with Congress, though lawmakers are ultimately free to heed or ignore them. Some say the panel should be empowered to make Medicare cost reductions.

President Barack Obama says he is open to ideas about "giving special consideration to the recommendations of the Medicare Payment Advisory Commission (MedPAC), a commission created by a Republican Congress. Under this approach, [the panel's] recommendations on cost reductions would be adopted unless blocked by a joint resolution of Congress."

In a June 3 letter to Senate health committee chairmen Max Baucus (Mont.) and Edward Kennedy (Mass.), the president said, "This is similar to a process that has been used effectively by a commission charged with closing military bases and could be a valuable tool to help achieve health care reform in a fiscally responsible way."

A greater role for MedPAC is envisioned in a bill (S. 1110), introduced by Sen. John D. Rockefeller (D-W.Va.), to transform it from an advisory body into an executive branch agency that would determine provider payments but not deliver payments to providers. Under the bill, the Centers for Medicare and Medicare Services would consult with MedPAC and implement provider payment changes through normal regulatory processes.

G-2 Conference Calendar

Sept. 23-25
Our 27th Annual Lab Institute
Advancing in the Eye of the Storm
Crystal Gateway Marriott Hotel, Arlington, Va.

Oct. 19-21
Integrated Diagnostics Services Conference
How to Leverage the Convergence of the Lab, Pathology, Imaging, and IT
Crystal Gateway Marriott Hotel, Arlington, Va.

Nov. 12
Lab Leaders Summit
Driving Growth in Your Business
The Princeton Hotel, New York City

For details, including savings for "early bird" registrants, go to www.g2reports.com

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